Amendments

Please amend the application as follows:

In the Claims:

Please cancel claims 2-7 without prejudice to or disclaimer of the subject matter contained therein.

Please amend the claims as follows:

1. (Once Amended) A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 5.

Remarks

I. Support for the Amendments

Support for the foregoing claim amendments may be found throughout the specification, and in the original claims. Specifically, support can be found at page 9 through page 15. No new matter was added by way of these amendments.

II. Status of the Claims

By the foregoing amendments, claim 1 has been amended to recite the elected SEQ ID NOs, and non-elected claims 2-7 have been canceled. Upon entry of the foregoing amendments claim 1 is pending in the present application.

III. Summary of the Office Action

In the Office Action dated May 16, 2001, the Examiner has made five rejections of the claims. Applicants respectfully offer the following remarks to overcome or traverse each of the elements of the Office Action.

IV. The Rejection of Claim 1 Under 35 U.S.C. § 101

In the Office Action at pages 3-6, the Examiner has rejected claim 1 under 35 U.S.C. § 101, for allegedly lacking a patentable utility. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification described multiple utilities for the present invention, including "to produce a plant containing reduced levels of a protein (pg. 11), determining an association between polymorphisms and a plant trait (pg. 11), isolating a genetic region or nuclei[c] acid (pg. 11), determining a level or pattern in a plant cell of a protein in a plant (pg. 11), determining a mutation in a plant whose presence is predictive of a mutation affecting a level or pattern of a protein (pg. 13), as molecular tags to isolate genetic regions, isolated genes, map genes, and determine gene function (pg. 14), identifying tissues (pg. 14), [t]he specification states that the nucleic acid ESTs of the present invention can enable the acquisition of molecular markers, which can be used in breeding schemes, genetic and molecular mapping and cloning of agronomically significant genes (pg. 31)." Office Action, at page 5. However, the Examiner contends that none of these utilities constitute a "substantial" or "specific" utility. Applicants respectfully disagree with this assertion.

It is well established that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d

951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. In addition to the utilities described by the Examiner (quoted above), the claimed nucleic acid molecules are useful for determining the presence and/or identity of polymorphisms, measuring the levels of an mRNA in a sample, determining the location of a corresponding DNA sequence on a physical or genetic map, probing for other molecules, generating primers, obtaining other nucleic acid molecules from the same species, obtaining related protein coding sequences, obtaining promoters and other flanking genetic elements, screening cDNA genomic libraries, obtaining nucleic acid homologies, detecting and characterizing gene expression, etc. *See* page 30 under "Uses of the Agents of the Invention."

Many of these uses are directly analogous to a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.,* the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather the Examiner attempts to undermine the existing utilities by stating, "[t]hese are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acids being claimed." Office

Action, at page 5. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stifung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Moveover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 306 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 163 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

As noted above, the claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and locate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified be any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit a ball in

a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claim 1 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

V. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

In the Office Action, at page 7, the Examiner has rejected claim 1 as not being enabled by the specification, because the claimed invention allegedly lacks utility. Applicants respectfully traverse this rejection. This rejection has been overcome by the foregoing arguments regarding utility. Thus, this rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal are respectfully requested.

VI. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

In the Office Action, at pages 7-8, the Examiner has rejected claim 1 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Applicants respectfully traverse this rejection.

Although the Examiner admits that the "specification teaches the nucleic acid of SEQ ID NO: 1-5", Office Action, at page 7, the Examiner contends that Applicants have not adequately described the claimed genus of nucleic acid molecules. Applicants respectfully disagree with this contention.

An adequate written description of a genus of nucleic acids, as recited in claim 1 may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules be disclosed. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996) (the written description requirement is met if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

The Examiner further contends that the skilled artisan would not recognize that the applicant was in possession of the claimed genus. According to the Examiner, proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the

actual disclosure of every sequence encompassed by that claim. In support of this proposition, the Examiner cites no case law, but appears to rely on *Regents of the University of California v. Eli Lilly and Co*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398, (Fed. Cir. 1997). Applicants respectfully disagree. In *Eli Lilly* the court found that claims to a vertebrate cDNA coding insulin were inadequately described. However, the present case is clearly different. Specifically, the present claims "distinguish the claimed genus from others" and define "structural features commonly possessed by members of the genus that distinguishes them from others," unlike the claims at issue in *Eli Lilly*. *Id.* at 1568-69 ("a cDNA is not defined or described by the mere name 'cDNA'...but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA.").

In particular, Applicants have provided a detailed chemical structure, i.e., the nucleic acid sequences of SEQ ID NOs: 1-5. Moreover, nucleic acid molecules falling within the scope of the present claims are readily identifiable- they comprise a nucleic acid molecule having the sequence selected from the group consisting of SEQ ID NO: 1-5. The fact that the nucleic acid molecules may comprise additional sequences or variations is not a proper ground for rejection. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for claim 1. Thus, claim 1 satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

VII. Rejections of Claim 1 Under 35 U.S.C. § 102(a)

In the Office Action at page 9, the Examiner has rejected claim 1 under 35 U.S.C. § 102(a), for allegedly being anticipated by Walbot (Genbank accession no. AI978199), ("Walbot 1") and by Walbot (Genbank accession no. AI734448) ("Walbot 2"). Applicants respectfully traverse these rejections.

Neither reference anticipates the present claims. For a prior art reference to anticipate in terms of 35 U.S.C. §102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.,* 850 F.2d 675, 677, 7 U.S.P.Q. 2d 1315, 1317 (Fed. Cir. 1988). *See also Kalman v. Kimberly Clark Corp.,* 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied,* 465 U.S. 1026 (1984). Applicants contend that neither Walbot 1 nor Walbot 2 teach every element of the claimed invention. The Examiner admits that the Walbot references do not expressly disclose the sequence of claim 1, but rather "differs from instant SEQ ID NO: 5 at a single position," (Walbot 1) and "differs from instant SEQ ID NO: 5 at two positions," (Walbot 2). However, the Examiner contends that Walbot 1 and Walbot 2 inherently anticipate claim 1, and asserts:

> [t]he nucleotide sequence is an inherent property of the nucleic acid and is only one means by which a nucleic acid may be characterized. Thus, if an error in sequencing has occurred, the nucleic acids of the instant application and Walbot are inherently the same.

Office Action at page 9, section 6, and page 10, section 7. Applicants respectfully disagree with this assertion as a matter of law.

It is established in the patent law that "to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is ***necessarily*** present in the thing described in the reference." *Continental Can Co. v. Monsanto Co.,* 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746,

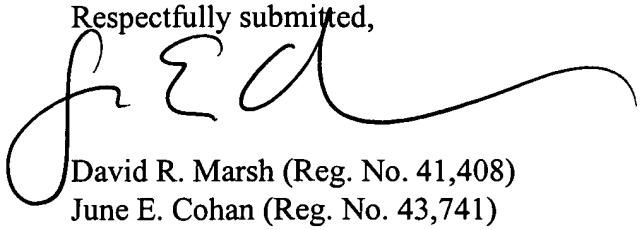
1749 (Fed. Cir. 1991). It is clear in this case that the nucleotide sequence disclosed in SEQ ID NO: 5 of the present invention is not actually or ***necessarily*** present in the nucleic acid sequence disclosed in either Walbot reference. Further, "[i]nherency...may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances (*e.g.*, sequencing errors) is not sufficient." *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981) (quoting *Hansgirg v. Kemmer*, 102 F.2d 212, 214, 40 U.S.P.Q. 665, 667 (C.C.P.A. 1939)). As such, claim 1 of the present invention is not expressly or inherently anticipated by Walbot 1 or Walbot 2. Reconsideration and withdrawal of these rejections is respectfully requested.

VIII. Summary

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,



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Version with markings to show changes made

In the claims:

1. A substantially purified nucleic acid molecule that encodes a plant protein or fragment thereof comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 5 [4013].